



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0829; FRL-9354-6]

Titanium Dioxide; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of titanium dioxide (CAS Reg. No. 13463-67-7) when used as an inert ingredient (Ultraviolet-stabilizer) (UV), at no more than 5% in pesticide formulations containing the active ingredient napropamide, used in or on growing crops. United Phosphorus, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to an existing requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of titanium dioxide.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0829, is available at <http://www.regulations.gov> or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located

in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001.

The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: David Lieu, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-0079; email address: lieu.david@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification

System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0829 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of

your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0829, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of November 9, 2011 (76 FR 69692) (FRL-9325-1), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7918) by United Phosphorus, Inc., 630 Freedom Business Center, Suite 402, King of Prussia, PA 19406. The petition requested that 40 CFR 180.1195 be amended by modifying an exemption from the requirement of a tolerance for residues of titanium dioxide (CAS Reg. No. 13463-67-7) when used as an inert ingredient, UV-stabilizer, at no more than 5% in pesticide formulations containing the active ingredient napropamide. That notice referenced a summary of the petition

prepared by United Phosphorus, Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special

consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for titanium dioxide including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with titanium dioxide follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by titanium dioxide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

A substantial proportion of the toxicity data provided in this unit has been taken from comprehensive reviews and publications from The International Agency for Research on Cancer (IARC), World Health Organization (WHO) and National Cancer Institute (NCI). The titanium dioxide acute toxicity studies show low toxicity near limit doses. Titanium dioxide is also not a skin sensitizer. A 28-day lung instillation studies demonstrated slight fibrogenic effects comparable to that of a nuisance dust. A 90-day lung instillation study showed statistically significant signs of inflammation immediately after exposure but they were absent after 1-month. Many subchronic and chronic oral toxicity studies were performed on different species including rats, mice, dogs, cats, rabbits and guinea pigs. The doses ranged up to 100,000 parts per million (ppm) (5,000 milligrams/kilograms/day (mg/kg/day)) with study durations up to 2 years. None of these studies showed mortality or adverse toxicological effects caused by titanium dioxide. No reproductive or developmental studies were available for review in the toxicity database. Mutagenicity studies including sister chromatid exchange assays, *in vitro* micronucleus

assays, comet assays, reverse mutation tests and chromosome aberration test produced mixed results but overall these tests showed that titanium dioxide is not mutagenic. Titanium dioxide is not carcinogenic via the oral, intraperitoneal or subcutaneous routes of exposure in rats or mice; however, there is concern via the inhalation route. In inhalation studies, tumors present in the lungs are thought to have been a localized fibrogenic effect caused by overloading of the lungs with high concentrations of titanium dioxide particles over a prolonged period of time. The concentrations used in these studies are near limit dose levels. Actual environmentally anticipated exposures of titanium dioxide based on the use patterns of products that would contain titanium dioxide are orders of magnitude less than that allowed by the Occupational Safety and Health Administration's (OSHA) Permissible Exposure Limit (PEL). Specific information on the studies received and the nature of the adverse effects caused by titanium dioxide can be found at <http://www.regulations.gov> in the document "Titanium Dioxide (TiO₂). Risk Assessment to Support Proposed Amendment to Exemption from the Requirement of a Tolerance When used as an Inert Ingredient in Pesticide Formulations under 40 CFR 180.1195," in docket ID number EPA-HQ-OPP-2011-0829.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies on titanium dioxide via oral route of exposure clearly demonstrate lack of toxicity. The several studies in mice, rats, dogs, cats, rabbits and other species of varying durations do not indicate toxicity at very high doses (e.g. 50,000 ppm or 2,500 mg/kg/day dietary exposure for 2 years in rats). No end point of concern via oral route of exposure has been identified in the available database. Therefore, dietary exposure was not estimated. This conclusion is in agreement with the

conclusion of the WHO Committee on Food Coloring Materials that no Acceptable Daily Intake (ADI) need be set for the use of titanium dioxide based on the range of acute, sub-acute and chronic toxicity assays, all showing low mammalian toxicity. Similarly, no significant toxicity of titanium dioxide is expected via the dermal route of exposure. The available inhalation studies indicate that the primary toxicity of titanium dioxide is due to deposition of the inhaled particles and also suggest equivocal evidence of carcinogenicity due to prolonged exposure to titanium dioxide particles. No direct exposure to titanium dioxide particles is expected in pesticide napropamide formulations (less than 5% in formulations).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses and drinking water.* In evaluating dietary exposure to titanium dioxide, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from titanium dioxide in food as follows:

An exposure assessment for titanium dioxide was not conducted because no endpoint of concern was identified in the database.

2. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Based on the use pattern provided by the registrant and use limitations/restrictions there are no residential uses and thus no residential exposures are expected.

3. *Cumulative effects from substances with a common mechanism of toxicity.*
Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish,

modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found titanium dioxide to share a common mechanism of toxicity with any other substances, and titanium dioxide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that titanium dioxide does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

There were no significant hazards identified in the available data at levels at or below the limit dose of 1,000 mg/kg/day. Thus, due to its low potential hazard and the

lack of a hazard endpoint, it was determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for titanium dioxide. For the same reasons that a quantitative risk assessment based on a safety factor approach is not appropriate for titanium dioxide, an FQPA SF is not needed to protect the safety of infants and children.

E. Aggregate Risks and Determination of Safety

Titanium dioxide has two exemptions from the requirement of a tolerance: pesticide formulations applied to growing crops, 40 CFR 180.920; and pesticide formulations applied to animals, 40 CFR 180.930. Titanium dioxide is also approved for use as a colorant in food (21 CFR 73.575), in drugs (21 CFR 73.1575), and in cosmetics (21 CFR 73.2575; 21 CFR 73.3126). There has also been a previous exemption from requirement of a tolerance for residues in or on growing crops, when used as an inert ingredient (UV protectant) in microencapsulated formulations of the insecticide lambda-cyhalothrin at no more than 3.0% by weight or the formulations (40 CFR 180.1195). There was also no aggregate risk assessments performed since there was no single exposure, dietary or drinking water endpoints of concern.

Taking into consideration all available information on titanium dioxide, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to titanium dioxide under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.1195 for residues of titanium dioxide when used as an inert ingredient (UV stabilizer) in pesticide formulations of napropamide at no more than 5% of the product formulation is considered safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for titanium dioxide.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.1195 for titanium dioxide (CAS Reg. No.13463-67-7) when used as an inert ingredient (UV-stabilizer) at no more than 5% in pesticide formulations containing the active ingredient napropamide in pesticide formulations.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 18, 2012.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1195 is revised to read as follows:

§ 180.1195 Titanium dioxide.

Titanium dioxide (CAS Reg. No. 13463-67-7) is exempted from the requirement of a tolerance for residues in or on growing crops, when used as an inert ingredient (UV protectant) in microencapsulated formulations of the insecticide lambda cyhalothrin at no more than 3.0% by weight of the formulation and as an inert ingredient (UV-stabilizer) at no more than 5% in pesticide formulations containing the active ingredient napropamide.